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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/555,895	11/04/2005	Jeffrey Yeung	325-003US	2268

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EXAMINER	
EISENBERG, REBECCA E	
ART UNIT	PAPER NUMBER
3763	
MAIL DATE	DELIVERY MODE
08/02/2011	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/555,895	YEUNG ET AL.	
	Examiner	Art Unit	
	REBECCA E. EISENBERG	3763	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *06/21/2011*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-55,75-88 and 91-101* is/are pending in the application.

4a) Of the above claim(s) *75-88 and 91-98* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-55 and 99-101* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 112

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claim 1 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

3. Claim 1 recites the limitation "said conduit" in line 4. It should be "a conduit". There is insufficient antecedent basis for this limitation in the claim.

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. Claims 1, 6-20, 99, 101 are rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Patent No. 6,224,630 to Bao et al. (Bao).

Bao teaches a deployment for deploying a conduit with a tubular sheath for puncturing the interverteral disc (where the sheath is capable of puncturing the disc), a conduit (10) sized and configured to fit at least partially within the tubular sheath, a plunger sized to at least partially fit within the tubular sheath and designed to deploy the conduit, the deployment device with a first position wherein said conduit is located at least partially within the tubular sheath and the second potion having the conduit expelled from the

tubular sheath and implanted into the disc (Col. 3 ln. 15-22, Col. 4 ln. 60-67, Col. 5 ln. 20-30, Col. 9 ln. 12-22, Col. 14 ln. 1-11, 50-65). Bao teaches a coating on a tubular sheath (Col. 9 ln. 12-22), where the coating is an antibiotic (col. 9 ln. 12-41). The conduit is a tube formed of a biocompatible material (Col. 6 ln. 14-40) the conduit is a sponge formed of a biocompatible material (Col. 5 ln. 31-46, Col. 6 ln. 14-40), the conduit has a plurality of protrusions (Col. 7 ln. 61-67), and the protrusions are chosen from the group consisting of flanges knots and rings (Col. 7 ln. 61-67). Bao teaches the conduit formed of a biodegradable material (Col. 6 ln. 13-39), the conduit is formed of a non-degradable material (Col. 5 ln. 48-58), chosen from polytetrafluoroethylene (Col. 5 ln. 48-58). Bao teaches the conduit formed of a degradable material include collagen (col. 6 ln. 13-47), the conduit has a coating of cells (Col. 9 ln. 12-22). Bao teaches the pore size is between 200 microns to 10 nanometers (Col. 7 ln. 31-44), the conduit has channels with a diameter of 200 microns to 10 nanometers (Col. 7 ln. 31-44). Bao teaches the conduit with two ends, one end is located within a disc and the other is locatable within the patient's bodily circulation allowing conduit to establish exchange of waste and nutrients between the disc and bodily circulation (Col. 3 ln. 15-22, Col. 4 ln. 60-67, Col. 5 ln. 20-30, Col. 9 ln. 12-22, Col. 14 ln. 1-11, 50-65). Bao teaches the conduit is a linear porous filament (Col. 3 ln. 15-22, Col. 4 ln. 60-67, Col. 5 ln. 20-30, Col. 9 ln. 12-22, Col. 14 ln. 1-11, 50-65).

Claim Rejections - 35 USC § 103

6. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

7. Claims 2-5, 24-33, 35-40, 45-49, 51-54, 100 rejected under 35 U.S.C. 103(a) as being unpatentable over Bao in view of Mickley.

Bao teaches the claim limitation of claim 1, but fails to explicitly teach a tubular sheath with a beveled tip.

Mickley teaches a sheath with a beveled tip (Fig. 1, col. 4, lines 35-67, cols. 5-11 and col. 12, lines 1-10).

It would have been obvious to one of ordinary skill in the art at the time of the invention to have the sheath with a beveled tip of Mickley in order to allow for easier entrance into the spinal column.

Bao teaches the claim limitation of claim 1, but fails to explicitly teach a needle located at least partially within the tubular sheath, conduit located at least partially within said needle, or the conduit partially around said needle.

Mickley teaches a needle 136 located partially within the sheath, a conduit partially within said needle, and a conduit 126 partially around the needle Fig. 1, col. 4, lines 35-67, cols. 5-11 and col. 12, lines 1-10).

It would have been obvious to one of ordinary skill in the art at the time of the invention to have a needle located at least partially within the tubular sheath, conduit located at least partially within said needle, or the conduit partially around said needle in order to ensure higher accuracy during insertion of the device into the disc.

Bao teaches a deployment for deploying a conduit with a tubular sheath for puncturing the interverteral disc (where the sheath is capable of puncturing the disc), a conduit (10) sized and configured to fit at least partially within the tubular sheath, a plunger sized to

at least partially fit within the tubular sheath and designed to deploy the conduit, the deployment device with a first position wherein said conduit is located at least partially within the tubular sheath and the second potion having the conduit expelled from the tubular sheath and implanted into the disc (Col. 3 ln. 15-22, Col. 4 ln. 60-67, Col. 5 ln. 20-30, Col. 9 ln. 12-22, Col. 14 ln. 1-11, 50-65), but fails to teach a first elastic needle with a straightened position and a curved position.

Mickley discloses a device for deployment of a conduit including a needle 136 located partially within the sheath and having a beveled tip (Fig. 1, col. 4, lines 35-67, cols. 5-11 and col. 12, lines 1-10).

It would have been obvious to one of ordinary skill in the art at the time of the invention to have a needle located at least partially within the tubular sheath in order to insure higher accuracy during insertion of the device into the disc and to help navigate potentially tortuous tissues.

Bao in view of Mickley teach the claim limitations of claim 24, where Mickley discloses a device for deployment of a conduit including: a sheath 106 having a sharp tip; a needle 136 located partially within the sheath and having a beveled tip; a conduit 126 partially around the needle; and a plunger or actuator to deploy the conduit (Fig. 1, col. 4, lines 35-67, cols. 5-11 and col. 12, lines 1-10).

Bao in view of Mickley teach the claim limitations of claim 24, but fails to teach the tubular sheath and needled having non round cross sections, tubular sheath and needle having similar cross section shapes, and the sheath having oval cross sections.

It would have been obvious to one of ordinary skill in the art at the time of the invention to have non round cross sections in order to allow for the navigation into difficult locations and as a matter of design choice based on the desired final destination of the device and conduit.

Bao in view of Mickley teach the claim limitations of claim 24, where Mickley teaches a second elastic needle located at least partially around a first elastic needle (see fig. 1).

Bao in view of Mickley teach the claim limitations of claim 32, but fails to teach the two needles having similar curvatures and oriented in similar directions.

It would have been obvious to one of ordinary skill in the art at the time of the invention to have two needles having similar curvatures and oriented in similar direction in order to allow for the navigation into difficult locations and as a matter of design choice based on the desired final destination of the device and conduit.

Bao in view of Mickley teach the claim limitations of 24, but fail to teach a ramp within the tubular sheath.

It would have been obvious to one of ordinary skill in the art at the time of the invention to have a ramp within the tubular sheath in order to allow for smaller conduits to be inserted within the sheath without them shifting during insertion into the patient.

Bao in vie of Mickley teach the claim limitations of claim 32, but fail to teach the location of the ramp.

It would have been obvious to one of ordinary skill in the art at the time of the invention to have placed the ramp at the distal end of the tubular sheath and proximate a convex side in order to allow for proper placement and locality of the conduit.

Mickley discloses that conduit 126 can be made of any of various metallic and non-metallic biocompatible materials, including non- biodegradable materials such as polypropylene or polyurethane or biodegradable materials such as polycaprolactone. Bao teaches a plunger for deploying the conduit, a coating on a tubular sheath (Col. 9 ln. 12-22), where the coating is an antibiotic (col. 9 ln. 12-41). The conduit is a tube formed of a biocompatible material (Col. 6 ln. 14-40) the conduit is a sponge formed of a biocompatible material (Col. 5 ln. 31-46, Col. 6 ln. 14-40), the conduit has a plurality of protrusions (Col. 7 ln. 61-67), and the protrusions are chosen from the group consisting of flanges knots and rings (Col. 7 ln. 61-67). Bao teaches the conduit formed of a biodegradable material (Col. 6 ln. 13-39), the conduit is formed of a non-degradable material (Col. 5 ln. 48-58), chosen from polytetrafluoroethylene (Col. 5 ln. 48-58). Bao teaches the conduit formed of a degradable material include collagen (col. 6 ln. 13-47), the conduit has a coating of cells (Col. 9 ln. 12-22). Bao teaches the pore size is between 200 microns to 10 nanometers (Col. 7 ln. 31-44), the conduit has channels with a diameter of 200 microns to 10 nanometers (Col. 7 ln. 31-44). Bao teaches the conduit with two ends, one end is located within a disc and the other is locatable within the patient's bodily circulation allowing conduit to establish exchange of waste and nutrients between the disc and bodily circulation (Col. 3 ln. 15-22, Col. 4 ln. 60-67, Col. 5 ln. 20-30, Col. 9 ln. 12-22, Col. 14 ln. 1-11, 50-65).

8. Claims 21-22 and 55 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bao in view of Mickley and Gough.

Bao and Mickley teach the claim limitations of claim 1, but fails to explicitly teach a tube located around a central portion of the conduit.

Gough teaches a tube located around a central portion of the conduit (Col. 6 ln. 26-41).

It would have been obvious to one of ordinary skill in the art at the time of the invention to have a tube around a central portion of the conduit in order to reinforce the structure and to provide stability to the conduit.

Bao in view of Mickley and Gough teach the claim limitation of claim 21, but fails to teach the material of the tube.

It would have been obvious to one of ordinary skill in the art at the time of the invention to have the tube made of polyurethane as it is a well known material with which biocompatible tubes and catheters are made from.

Bao and Mickley teach the claim limitations of claim 24, but fails to explicitly teach a tube located around a central portion of the conduit.

Gough teaches a tube located around a central portion of the conduit (Col. 6 ln. 26-41).

It would have been obvious to one of ordinary skill in the art at the time of the invention to have a tube around a central portion of the conduit in order to reinforce the structure and to provide stability to the conduit.

9. Claim 23 is rejected under 35 U.S.C. 103(a) as being unpatentable over Bao.

Bao teaches the claim limitations of claim 1, but fails to teach the conduit coated with a fibrous tissue inhibitor.

It would have been obvious to one of ordinary skill in the art at the time of the invention to have a fibrous tissue inhibitor in order to prevent scar tissue from forming around the conduit.

10. Claim 34 is rejected under 35 U.S.C. 102(b) as being anticipated by Bao in view of Mickley and Makower et al. (Makower).

Bao in view of Mickley teach the claim limitiatons of claim 24, but fail to teach an opening extending through the wall of a tubular sheath proximal a distal end.

Makower teaches a conduit deployment device including: a sheath 192 with a side opening 198; a needle 102; and a conduit 194 (Fig. 6e and col. 32, lines 4-36).

It would have been obvious to one of ordinary skill in the art at the time of the invention to have an opening in the wall of a tubular sheath in order to allow for varied placement of the conduit within the disc.

11. Claims 41-44 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bao in view of Mickley and Rowland.

Bao in view of Mickley disclose all elements of the claimed invention except for a coating on the the needle.

Rowland teaches coating medical instruments to reduce friction. Rowland also teaches including therapeutic agents such as inhibitors of cell or tissue growth in the coating (col. 1, lines 28-68 and col. 2).

Accordingly, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have provided a coating on the sheath of the Bao and Mickley device, as taught by Rowland et al., to reduce friction and/or inhibit tissue growth.

Response to Arguments

12. Applicant's arguments with respect to claims pending have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to REBECCA E. EISENBERG whose telephone number is (571)270-5879. The examiner can normally be reached on Monday - Friday 9:30 AM - 7:00 PM EDT.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, NICHOLAS LUCCHESI can be reached on (571)272-4977. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/REBECCA E EISENBERG/
Examiner, Art Unit 3763

/Nicholas D Lucchesi/
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